

REMARKS

1. The Amendments and the Support Therefor

Three claims (23-25) are canceled, three new claims (26-28) have been added, and claims 14 and 19 have been amended to leave claims 1-15 and 19-28 in the application. No payment should be due for the new claims because the number of claims canceled is equivalent to the number added, and payment for four independent claims – the number present in the current application – was submitted on April 29, 2009. No new matter is added by the amended and new claims, wherein:

- Claims 14 and 19: amended to address §112 issues.
- Claim 26: find support at (for example) page 5 lines 27 to 32 in combination with claims 1, 2 and 4.
- Claim 27: find support at (for example) page 5 lines 19 to 20.
- Claim 28: find support at (for example) page 11 lines 8 to 11.

2. Information Disclosure Statement (Form PTO-1449)

A form 1449 accompanies this Response, along with payment of the associated 37 CFR §1.17(p) fee. The cited references seem to be at least substantially cumulative to the *Buono et al.* reference cited in the Office Action, but kindly carefully consider the references for their relevance in any event.

3. Rejection of Claims 1-15 and 19-25 under 35 USC §112(1): Enablement

Kindly reconsider the rejections of claims 1-15 and 19-25, since one of ordinary skill can readily make and use the invention without undue experimentation. These rejections read as follows (from pages 3-5 of the Office Action):

The "formula" at para. 62 of the printed publication of the instant applicant is called into question by the Examiner. Specifically, the formula requirement of a "factor of ambient compensation".

The disclosure of the instant applicant suggests at para. 64 that the "factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade, and refers to the increase in the subjects core body temperature for every perfect loss

of body weight, in temperate and hot climates respectively" and suggests at para. 43 "the factor of ambient compensation may be between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subject".

It is important to note this is the only written explanation of the "factor of ambient compensation".

The "factor of ambient compensation" is deemed simply a mythical number by the Examiner because it is beyond routine experimentation for one of ordinary skill in the art to determine how the factor is chosen. The logic behind exactly how the number is chosen is non-existent in the specification.

As stated above, the specification suggests that the "factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade" where the bounds of the factor of ambient compensation in centigrade are presented. The specification goes on to suggest the factor of ambient compensation "refers to the increase in the subjects core body temperature for every percent loss of body weight". However, how this reference is made is non-existent in the disclosure. The disclosure lacks how a reference is made. By simply stating a reference is made, a skilled artisan would be required to perform undue experimentation to determine how the reference is made.

Similarly, the specification suggests that the "factor of ambient compensation may be between 0.1 and 0.23" where the bounds of the factor of ambient compensation are presented, without corresponding to any particular unit type. The specification goes on to suggest the factor of ambient compensation "is determined in dependence on the temperature of the environment surrounding the subject". However, how the determination is made and how the determination depends on the temperature of the environment surrounding the subject is non-existent in the disclosure. The disclosure lacks how the determination is made and how the determination depends on the temperature of the environment surrounding the subject. By simply stating a determination is made and that the determination depends on a temperature, a skilled artisan would be required to perform undue experimentation to determine how the determination is made and how the determination depends on the temperature of the environment surrounding the subject.

In summary, the disclosure of the instant application fails to enable how the factor of ambient compensation works or how it is chosen, therefore, it is beyond routine experimentation of one of ordinary skill in the art and a skilled artisan would not be able to make use of the invention. The "factor of ambient compensation" is not enabled by the original disclosure.

These rejections are effectively stating that an ordinarily skilled artisan would not know how to set the factor of ambient compensation to a value between 0.1 (stated in the specification as being preferred for temperate climates) and 0.23 (stated in the specification as being preferred

for hot climates). With respect, *this assumes an extraordinarily unskilled artisan incapable of simple problem-solving, and is clearly false*. This is particularly so when it is considered that *the factor of ambient compensation is merely a constant scaling factor* used to scale output to a preferred numerical output range (as is also evident from the calculations discussed in the specification). Thus, one could just as readily choose a value of 0.001, or 1000, for the factor of ambient compensation; these would simply result in numerical outputs having large and unwieldy numbers of digits (which would require more digits on a digital display, and which are annoying to mentally process), but which nonetheless result in useful (though less convenient) hydration level measurements. Please review page 9 lines 1-17 (corresponding to pars. [0062]-[0064] of US Publ'n. 2008/0234600):

The calculation performed by the processor is carried out at regular intervals as follows:

$$[(\text{core body temperature current} - \text{core body temperature normal}) \times \text{weight}] / (\text{factor of ambient compensation} \times 100)$$

. . . . The factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade, and refers to the increase in the subject's core body temperature for every percent loss of body weight, in temperate and hot climates respectively.

Consider:

- In the foregoing formula, the “factor of ambient compensation” is just a constant divisor – and thus as a practical matter, *it merely serves as a constant scaling factor that adjusts the output up or down*. Thus, while an ambient compensation factor within the noted 0.1 and 0.23 range is preferred, one could just as well choose *any* nonzero number (though the noted range is preferred to obtain an output which has a reasonable number of digits for display).¹ The relevance / effect of the ambient compensation factor would be

¹ Consider the case of ambient compensation factors valued between 0.1 and 0.23, and users varying between 100 lbs (45.5 kg) and 200 lbs (90.9 kg) in weight. If we look at the resulting extremes in the formula:

- Lowest weight and highest ambient compensation factor yield the formula of:
$$1.98 \times (\text{core body temperature current} - \text{core body temperature normal})$$
- Highest weight and lowest ambient compensation factor yield the formula of:
$$9.09 \times (\text{core body temperature current} - \text{core body temperature normal})$$

In other words, regardless of weight and ambient temperature, the formula returns values of roughly two to nine times the difference between the current core temperature and the normal / starting core temperature. Regardless of whether the scaling factor is 2, 9, or a value in between, as the user engages

apparent to one of ordinary skill upon merely observing the formula. From there, it is a profoundly simple matter for the ordinary artisan to simply choose an ambient compensation factor which yields output within a desired range (e.g., having a desired number of digits) for any given ambient temperature.

- Further, as noted in the specification, the “factor of ambient compensation” is “valued between 0.1 and 0.23 degrees,” with the lower and upper values being set “*in temperate and hot climates respectively*.” Thus, an ordinary artisan could readily set the ambient compensation factor by using the 0.1 value at a presumed temperate climate value of 0 degrees C (this being an arbitrary example), and using the 0.23 value at a presumed hot climate value of 30 degrees C (as another arbitrary example), and scaling the ambient compensation factor as appropriate for values therebetween in accordance with a simple linear interpolation:

$$\text{Ambient Compensation Factor} = 0.1 + \frac{0.23 - 0.1}{30 - 0} \text{ Temp.}$$

From there, if it turns out that the presumed “temperate” 0 degree temperature and the presumed “hot climate” 30 degree temperature do not yield an output number which is conveniently scaled – e.g., if the artisan prefers output scaled between 1 and 100 – it would by no means require “undue experimentation” for the artisan to adjust the slope in the foregoing formula (i.e., adjust the ambient compensation factor).

To summarize the foregoing, an artisan can scale the ambient compensation factor between 0.1 for temperate climates and 0.23 at hot climates in pretty much any manner that he/she wishes. This will merely affect the range of the output hydration measurement. If the artisan gets output in a range that’s inconveniently high, he/she may increase the ambient compensation factor to shrink the range; conversely, if the output range is inconveniently low, he/she may decrease the ambient compensation factor to increase the range (with these steps being profoundly simple, and in no way constituting “undue experimentation”). *These points are exceedingly evident from*

in activity, he/she will tend to see higher number (and thus an indication of a higher need for hydration) as the temperature difference rises from its starting value (which should be at or near zero, since at the start of activity, the user’s current core temperature should be at or near normal).

review of the formula, and the rejections assume the ordinary artisan to be incompetent at basic mathematics. Kindly withdraw the rejections.

4. Rejection of Claims 1-13 and 23 under 35 USC §112(1) for “Too Broad (Undue Breadth)”

Kindly withdraw or clarify these rejections. Initially, it is unclear whether these are written description rejections, enablement rejections, both of these, or something else. “Undue breadth” is not a recognized form of 35 USC §112(1) rejection under MPEP 2161 *et seq.*, and by stating that “[o]ne having an ordinary skill in the art would not know what is included with the claims and what is excluded by the claims, when the claims are read in light of the specification,” the rejections also seem to invoke §112(2). If the rejections are maintained, kindly clarify.

Otherwise, looking to the bases for the rejections:

A skilled artisan would find the bounds of the claim indefinite as it is not known if the limitations "subject's weight" and a "factor of ambient compensation" are included with claim 1 to provide a hydration level when the claim is read in light of the specification, because such limitations are required for calculating the hydration level.

By the plain language of claim 1, weight and ambient compensation factors are not mandatory, and claim 1 is clear and definite in this respect. Further, looking to the specification (and the discussion in the foregoing Section 3 of this Response), note that both ambient compensation factor and weight merely serve as scaling factors in the aforementioned formula: regardless of the user's weight (whatever its amount, and whether in pounds, kilograms, or other units), and regardless of the ambient compensation factor chosen, the formula will nonetheless yield a measurement of hydration status which depends on the difference between current temperature and normal / starting temperature. Thus, weight and ambient compensation factor are *not* (as alleged by the rejection) “required for calculating the hydration level” – they can effectively be disregarded (though this is not preferred). As a simple example, the invention could simply output the difference between current core temperature and normal / starting core temperature as a measure of hydration. The problem with this approach is that the output might only be (for

example) in the range of 0.01 - 1.0 or so, which is why it's useful to scale this into a higher range.

Further, to the extent that the rejections appear to complain that weight and ambient compensation factors should be added to the claims, it is well settled that there is no requirement that an applicant claim an invention in such a manner that every feature described in the specification must be recited. See, e.g., *Carl Zeiss Stiftung v. Renishaw plc*, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991):

As one of our predecessor courts stated, "it is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter," as it is "entirely appropriate, and consistent with §112, to present claims to only [one] aspect." *Bendix Corp. v. United States*, 600 F.2d 1364, 1369, 220 Ct. Cl. 507, 514, 204 USPQ 617, 621 (1979).

See also *Rodime PLC v. Seagate Technology Inc.*, 50 USPQ2d 1429, 1434 (Fed. Cir. 1999) ("A claim need not claim every function of a working device. Rather, a claim may specify improvements in one function without claiming the entire machine with its many functions."); *Reiffin v. Microsoft Corp.*, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000):

It is standard for applicants to provide claims that vary in scope and in content, including some elements of a novel device or method, and omitting others. See Irving Kayton, 1 Patent Practice (6th ed.) 3.1, 3.3 (1995):

[P]atent practitioners typically draft a series of claims approximating a spectrum of patent protection. . . . The first way in which a claim may be made narrower is by adding a limitation to it in the form of an additional element.

Claiming an invention in this manner does not raise an issue of compliance with Section 112 Para.1. Indeed, the "omitted element test" threatens this venerable practice, which is also summarized in Ernest B. Lipscomb, III, [1919] 3 Lipscomb's Walker on Patents 290-91 (1985):

[A] claim may cover an invention embracing the entire process, machine, manufacture, or composition of matter which is described in the specification, or it may cover such sub-processes or such sub-combinations of the invention as are new, useful and patentable.

See, e.g., *Special Equipment Co. v. Coe*, 324 U.S. 370 (1945) (reversing the rejection of a sub-combination claim directed to the previously claimed invention less one element). While the specification must of course describe the claimed invention, it is well established that the claims need not include every component that is described in the specification. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 [128 USPQ 354] (1961) (There is "no legally recognizable or protected 'essential' element . . . in a combination patent.").

Thus, it is acceptable for claim 1, and the claims dependent therefrom, to omit weight and ambient compensation factors.

5. Rejection of Claims 19-22 and 25 under 35 USC §112(1): Written Description

These rejections state (in relevant part):

The Examiner notes that the Applicant was not in possession of hydration monitoring "without reliance on any measured electrical properties of the subject's body" as set forth in claim 19. . . .

The Examiner notes that the Applicant was not in possession "only" obtaining measurements from the subject by an earpiece [in relation to claim 21]

The Examiner notes that the Applicant was not in possession of calculating the hydration level "with reliance" or "independently from "the subject's heart rate"[in relation to claims 23-25]. The Examiner notes any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. [The foregoing claims] do not have basis in the original disclosure and is being rejected for failing to comply with the written description requirement.

The citation to *In re Johnson* is not understood, as the *Johnson* case (and more specifically the discussion on the cited pages of *Johnson*) seems irrelevant here. Further, while the rejections state that any limitation "must have basis in the original disclosure," this does not mean that the claimed matter must be explicitly described in the specification, with the claims and specification using the same terminology. Rather, as noted in MPEP 2163.02, "the fundamental factual inquiry [of the written description requirement] is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." Thus, there are numerous cases wherein "negative limitations" which were not stated in the specification were nonetheless found to be compliant with §112(1), since it was apparent from the specification that the applicant had nonetheless invented the claimed matter. See, e.g., *Ex parte Parks*, 30 USPQ2d 1234 (Bd. Pat. App. & Inter. 1993) (addition of the term "conducted in the absence of a catalyst", which did not appear in the original disclosure, was not new matter because the absence would be evident to those of ordinary skill); *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989) (term "not permanently fixed," while not literally disclosed, was not new matter in view of absence of

description in specification of permanently fixed microcapsules).

Here, the situation is the same as in the *Parks* and *Wright* cases: it is abundantly clear from a review of the specification that the applicant was in possession of the claimed matter at the time of filing. Regarding claim 19, the application plainly discusses a hydration monitor calculating hydration level from measured core body temperature “without reliance on any measured electrical properties of the subject’s body”; such a calculation is illustrated by the aforementioned formula, and no use of electrical properties of the body is described or implied. Similarly, regarding claim 21, the application describes use of temperature measurements from the earpiece without use of any measurements obtained elsewhere. These claims are therefore compliant with §112(1) in accordance with cases such as *Parks* and *Wright*.

6. Rejection of Claims 14, 15, and 19 under 35 USC §112(2)

The rejections of claims 14-15 should be withdrawn, particularly in view of the amendments to claim 14. As per MPEP 2173.02, the definiteness requirement of 35 USC §112(2) merely requires that an ordinary artisan must reasonably be able to determine what is included within the claims, and what is excluded by the claims, when the claims are read in light of the specification. Here, claims 14-15 are clear and understandable, particularly when read in light of the specification.

As for the rejections of claims 14 and 19 in view of alleged “omitted essential structural cooperative relationships,” with these rejections allegedly being supported by MPEP 2172.01, note that this section reads:

a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. See *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). But see *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965) (“[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result”); *Ex parte Huber*, 148 USPQ 447, 448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.).

The present claims do not “fail to interrelate essential elements” as per this section. Looking to the cited case of *In re Collier*, 158 USPQ 266, 267-268 (CCPA 1968), the applicant's claim recited a collection of elements in conjunction with recitations stating that the interaction between them was conditional (i.e., it may or may not occur). The applicant nevertheless contended he was claiming the interaction (i.e., he stated that he regarded the interaction as being his invention). The Court stated that such claims fail to comply with 35 USC §112(2) because they fail to distinctly recite what the applicant regards as his/her invention.

In *In re Venezia*, 189 USPQ 149, 151-152 (CCPA 1976), the Court of Customs and Patent Appeals, the predecessor to the Court of Appeals for the Federal Circuit, reversed the §101 and §112(2) rejections of a claim directed to a “kit” of elements wherein the elements were recited as being capable of future interaction (but the kit did not require present interaction, i.e., the elements may but need not interact). The Court there stated that:

[1] We have reviewed the disputed claims and in particular the language criticized by the examiner and the board. We conclude that the claims do define the metes and bounds of the claimed invention with a reasonable degree of precision and particularly, and that they are, therefore, definite as required by the second paragraph of section 112. As we view these claims, they precisely define a group or “kit” of interrelated parts. These interrelated parts may or may not be later assembled to form a completed connector. ... We see nothing wrong in defining the structures of the components of the completed connector assembly in terms of the interrelationship of the components, or the attributes they must possess, in the completed assembly. More particularly, we find nothing indefinite in these claims. One skilled in the art would have no difficulty determining whether or not a particular collection of components infringed the collection of interrelated components defined by these claims.

[2] We also fail to see any basis for rejecting appellant's claims for being incomplete in failing to recite a completed assembly. Appellant's invention is a “kit” of parts which may or may not be made into a completed assembly. Since all of the essential parts of the “kit” are recited in the claims, there is no basis for holding the claims incomplete.

In *Venezia*, the applicant made it clear that he regarded the invention to consist of the claimed elements whether or not they were assembled. Therefore, regarding *In re Collier*, the Court stated:

[3] There is no issue in this case of whether appellant is claiming what he regards as his invention. Moreover, although the claims before us contain some language which can be labeled “conditional,” this language, rather than describing activities which may or may not occur, serves to precisely define present structural attributes of interrelated

component parts of the "kit," such that a later assembly of the "kit" of parts may be effected. Thus, we find *In re Collier* inapposite to the claims presently before us.

Id. at 152. Here, claims 14 and 19 involve no conditional language, and thus *Venezia* and *Collier* (and MPEP 2173.02) are inapposite.

It is noted that the complaints raised by the Office Action are not complaints regarding indefiniteness – again, it is clear from the plain language of the claims what these claims cover, and what they do not cover. Rather, the Office Action’s complaints relate to the *breadth* of the claims, but breadth is not indefiniteness (MPEP 2173.04).

7. Rejection of Claims 14, 15, 19-22, and 25 under 35 USC §101

Regarding claims 14 and 15, these clearly require that the method be performed by a particular machine (a hydration monitor), and thus are compliant with §101.

Regarding claims 19-22 and 25, these are clearly addressed to a device (a hydration monitor), and merely contain functional limitations (which are valid limitations, as per MPEP 2173.05(g)). Nonetheless, claim 19 is amended to better clarify these points.

8. Rejection of Claims 1-12, 14, 15, and 19-25 under 35 USC §103 in view of U.S. Patent 7,306,565 to Fraden et al. and Buono et al. Publication

Kindly reconsider and withdraw these rejections. *Buono et al.* does not disclose calculation of hydration state from temperature, and rather describes an experimental study that seeks to determine the effects of a known hydration state (hypohydration, i.e., dehydration, or conversely euhydration, i.e., normal hydration). Referring to the abstract of *Buono*, heart rate (HR), rectal temperature (TRE), forearm blood flow, and oxygen uptake were measured for subjects of different hydration states. In other words, the effects of a *known* hydration state were studied: it was already known how hydrated the subject was, and the study sought to see how this affected other body parameters. It is not at all apparent from *Buono* that the results could be “reversed,” such that a subject’s temperature could be used to determine their hydration status: *Buono* establishes that dehydration can result in elevated temperature (and other) symptoms, but it does not follow that elevated temperature naturally indicates dehydration.

Further, *Buono* does not describe or suggest how to identify hydration state from core temperature even if core temperature was known. In addition, even if an artisan thought to use *Buono* to derive hydration state, why and how would he or she think to use temperature rather than the heart rate, blood flow, oxygen uptake, etc. used by *Buono*? (Moreover, given that to the extent *Buono* uses temperature, it uses *rectal temperature*, it seems unlikely that an artisan would contemplate use of *Buono*'s methods for a portable hydration monitor.)

In short, an ordinary artisan who did not know of Applicant's claimed arrangement, but who reviewed *Fraden et al.* and *Buono et al.*, would not in fact conceive or consider the claimed arrangement. As explained in MPEP 2142, for a claimed invention to be obvious, it must be such that it would be contemplated by an ordinary artisan who had no actual knowledge of the claimed invention:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Here, if this process is followed, with the claimed invention being placed out of mind and the cited references being objectively considered from the standpoint of an ordinary artisan, it cannot fairly be said that the ordinary artisan would contemplate or consider the claimed invention. It can be seen that one might consider using a *Fraden*-style device for use in measuring temperature in studies such as *Buono*'s, but it is not fairly seen how one would consider using *Buono* to convert the *Fraden* device into some form of hydration monitor. For the reasons noted above, one simply couldn't use *Buono* in this manner with any reasonable expectation of success.


9. New Claims 26-28

New claims 26-28 are submitted to be allowable over the currently-cited art for the reasons discussed above, i.e., if the cited art is objectively considered from the standpoint of one who did not know of the claimed invention, it can't fairly be said that one would conceive the claimed invention.

10. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



Craig A. Fieschko, Reg. No. 39,668
CUSTOMER NO. 25005
DEWITT ROSS & STEVENS S.C.
2 E. Mifflin St., Suite 600
Madison, WI 53703-2865
Telephone: (608) 395-6722
Facsimile: (608) 252-9243
cf@dewittross.com